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Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE THE OPINIONS OF DAVID GARCIA, M.D. AND MICHAEL STREIFF, M.D.

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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INTRODUCTION

Bard moved to exclude three specific categories of opinions from Drs. Garcia and Streiff (collectively the "Doctors"): (1) their "opinions" parroting Dr. Kessler's opinions; (2) their opinions regarding physician expectations and corporate conduct; and, (3) Dr. Garcia's case-specific opinions for Plaintiff Doris Jones. Plaintiffs, however, muddy the waters and argue issues not originally raised in Bard's motion.[1]

ARGUMENT

A. Plaintiffs Concede That Regurgitating Dr. Kessler's Opinions is Impermissible.

Plaintiffs concede in their Omnibus Statement that an expert can only rely on another expert's opinion "as long as the expert does not [1] merely act as a conduit for the other expert's opinion and [2] provided that the record shows that the expert independently evaluated the evidence supporting the other expert's opinion." (Dkt. No. 7799 at 7 (*citing In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053 (C.D. Cal. 2013))). Plaintiffs argue that the Doctors meet these two requirements, but do not address the numerous testimony citations in Bard's motion to the contrary.[2] The Doctors' testimony and expert report Addendum make clear that they are serving as simple conduits for Dr. Kessler's opinions, and that the Doctors have done no independent evaluation of the documents underlying Dr. Kessler's report.

First, for example, Plaintiffs accuse Bard of "an exaggerated mischaracterization" by asserting that the Doctors "regurgitated" Dr. Kessler's report. (Dkt. No. 7808 at 8.) Yet this is precisely what Dr. Garcia admitted to:

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[1] Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable Arguments In Opposition To Bard's Motions To Exclude Plaintiffs' Experts Under Rule 702 And *Daubert* (Doc. 7799). Plaintiffs' Omnibus Statement is not directed at any specific *Daubert* motion Bard filed. As such, Bard does not respond to the Omnibus Statement but instead will address any necessary issues in the context of its individual *Daubert* replies.

[2] However, Plaintiffs omit citing the second prong in their Opposition brief, and only superficially address this requirement as discussed below.

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> Q. So in drafting your addendum and kind of essentially regurgitating what Dr. Kessler found in his report, did you attempt to be as accurate as possible in describing Dr. Kessler's findings?
>
> A. I did.

(Mot. Ex. D, Garcia Dep., at 210:1-5.). Dr. Streiff also unequivocally testified that the Doctors did not modify Dr. Kessler's findings in any way, *i.e.*, they are serving as a mere conduit for Dr. Kessler's opinions:

> Q. Okay. But you didn't modify Dr. Kessler's findings in any, any way?
>
> A. I don't think so, no.
>
> Q. You didn't change any of his findings in the process of taking what you saw from his report and inserting it into your report?
>
> A. I don't – I don't think so. No, I don't recall doing that.
>
> Q. So you included seven numbered paragraphs in your report, you addendum repeating what Dr. Kessler himself said in his own report?
>
> A. Right.

(Mot. Ex. C, Streiff Dep., at 303:8-19.)

Also, Plaintiffs argue that Dr. Kessler's report only provided the Doctors with factual background and confirmed what they independently researched. (Pl. Br. at 8.) The Addendum itself belies this assertion. It goes beyond mere factual background by opining that Bard misled the FDA, and what Bard should and should not have done as a reasonable manufacturer. And, it paraphrases Dr. Kessler's opinions on pre-market regulatory submissions, and engineering and testing data far outside the practice of medicine, let alone the specialty of hematology, and paraphrases topics that the Doctors did not independently research:

- Bard mislead [sic] the FDA on the tendency of the Recovery filter to migrate…They represented to others and used an inappropriate minimum safety threshold and performance specification in their stability/migration in vitro studies…" (Mot. Ex. A, Rep., at p. 8, ¶ 1.)

- In light of these test results…Bard should not have marketed the filter since its performance was significantly poorer than the comparator, was not performing as intended, expected and represented prior to marketing and failed safety thresholds for migration… (*Id.* at ¶ 3.)

- Dr. Kessler also noted that perforation, filter fracture and tilting were significantly more common with the RNF than the SNF. Internal documents quoted in Dr. Kessler's report confirm that Bard knew of these deficiencies with the RNF but continued to market the device…In experimental testing [the G2] failed to meet the pre-specified standard of resistance to migration of greater than or equal to the SNF, so Bard changed and lowered the performance standard…" (*Id.* at p. 9, ¶ 5.)

Second, regarding the additional requirement of independent evaluation of the underlying facts, the extent of Plaintiffs' argument is, without citing the record, that the Doctors' "evaluation of the documents supporting the opinions of Drs. Kessler [sic] satisfies any reliability concerns the Court may have…" (Pl. Br. at 9.) However, the Doctors testified that they only reviewed *two* out of Dr. Kessler's more than 500 underlying documents: a medical article by Dr. Asch, and Dr. Betensky's expert report, which the Doctors also did not independently evaluate. (Mot. Ex. D, Garcia Dep. 212:8 – 213:6.) The Doctors admitted that they did not even *review* the underlying data, let alone evaluate it. Dr. Garcia was unequivocal:

> Q. Did you independently review and assess the reliability of the underlying data that Dr. Kessler relied on?
>
> A. Not beyond what I just told you [referring to the Asch article and Betensky report].
>
> Q. Okay. Did you check or test any of the assumptions that Dr. Kessler made about the data that he analyzed?
>
> A. No.
>
> Q. Did you verify the documents that Dr. Kessler reviewed actually show what he says they show?
>
> A. Not beyond what I just told you.

(*Id.*) Similarly, even if Dr. Streiff wanted to review the underlying documents, he did not have access to them:

> Q. You never actually pulled [the] underlying documents?
>
> A. True.

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> Q. Okay. Did you independently assess the reliability of the underlying data that Dr. Kessler relied on?
>
> A. I couldn't do that.
>
> ***
>
> Q. Okay. Did you verify the documents that Dr. Kessler reviewed actually showed what he says they showed?
>
> A. I – Again, I, I saw, read the report. I don't have the, the documents it was based on.

(Mot. Ex. C, Streiff Dep., 307:22 – 308:20.) In other words, the *only* document that the Doctors properly verified is the Asch article, a published version of the Recovery Filter clinical study. That one document cannot support any of the opinions copied from Dr. Kessler's report which include all the topics covered by Dr. Kessler, including regulatory disclosures and internal design, testing, and risk assessments.

And, in any event, the Doctors do not have the expertise to reliably verify Dr. Kessler's findings. The Doctors have no regulatory experience and are not familiar with the types of documents that Dr. Kessler relied upon to form his opinions or his methods. (Mot. Ex. C, Streiff Dep. 98:13 – 101:24; Mot. Ex. D, Garcia Dep. 83:16 – 85:12.) (*See also*, July 12, 2017, Deposition of Michael Streiff, at 277:10 – 278:17, attached as Exhibit A (testifying that he is not basing these opinions "on any particular regulation, standard, or law" and that they are "[a]ll personal opinions based on reading the Kessler report.")) As a result, the Doctors are not qualified to evaluate Dr. Kessler's opinions, and did not apply any reliable methodology or relevant experience to evaluating Dr. Kessler's regulatory opinions. These opinions should be excluded because the Doctors are merely a conduit for Dr. Kessler's opinions, and the Doctors did not independently evaluate the underlying data.

B. The Court Should Exclude Opinions On Physician Expectations and Corporate Conduct.

The Doctors' physician expectations opinions fall into two categories. First, that "manufacturers, like Bard, [should] continuously apprise the clinicians who order and

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implant IVC filters about their safety profile, performance characteristics, design problems, and internal risk assessments." (Pl. Br. at 4 (citing the Doctors' expert report).) In other words, Plaintiffs' argue that the Doctors should be able to opine that reasonable physicians expect to be told about the content of Dr. Kessler's report. Second, the Doctors opine that "questions remain as to whether [IVC filters generally] are effective, but concede that IVC filters should be implanted in patients with "acute venous thromboembolism with a contraindication to anticoagulation." (Mot. Ex. A, Rep., at p. 6.) In other words, Plaintiffs argue that the Doctors should be able to opine that reasonable physicians expect to be warned that filters are overprescribed.

1. The Doctors' Lack Qualifications For Their "Continuous Appraisal" Opinion, And Do Not Use Reliable Methodology.

Plaintiffs argue that the Doctors can opine on physician expectations for "clinicians who order and implant IVC filters" because this is a variation of the medical standard of care. Plaintiffs offer no legal basis for extending a reasonable physician standard, which is a required *element* of a medical malpractice claim, to a products liability claim in which the manufacturer's conduct, not the physician's, is at issue. The only authority relied on by Plaintiffs for such an expansion is *Saint Alphonsus Med. Ctr. - Nampa, Inc. v. St. Luke's Health Sys., Ltd.*, No. 1:12-CV-00560-BLW, 2014 WL 407446 (D. Idaho Jan. 24, 2014). But, *Saint Alphonsus* was an antitrust case addressing whether all physicians needed access to a shared electronic medical record system, and has nothing to do with the issues at hand.[3] And, even if this did somehow relate to a medical standard of care, Plaintiffs did not address the fact that neither of the Doctors "order [or] implant IVC filters." (Mot. 5-6.)

[3] Plaintiffs also cite *Primiano v. Cook*, 598 F.3d 558, 567 (9th Cir. 2010) for the generic proposition that an expert's opinion may be admitted when the expert adequately explained how he based his opinions on his experience, and used "the ordinary methodology of evidence-based medicine" to develop his opinion. This is also inapplicable to the Doctors' specific opinions, particularly because they opine that Bard should have disclosed internal company documents.

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Second, and most critically, Plaintiffs argue against a straw man of whether physician expectations regarding the use of Bard's filters is relevant. Bard argued a totally different issue: that, under the guise of "physician expectations," the Doctors intend to offer a corporate conduct opinion that Bard withheld information from physicians and the FDA based solely on their review of Dr. Kessler's report. This information, based on documents such as confidential regulatory filings as part of the 510(k) process, internal emails and memoranda, draft bench testing documents, draft PowerPoint presentations, and other documents that physicians never review or rely on, are never publicly disclosed by any manufacturer. In other words, the Doctors intend to opine on matters wholly unrelated to the plain meaning of "physician expectations" and far outside the scope of their expertise. Indeed, Plaintiffs concede that the Doctors "used Dr. Kessler's opinions to further demonstrate not only that evidence of IVC filters' efficacy does not exist, but that Bard was aware of this fact." (Pl. Br. at 9.)

Courts in this circuit have held that "it is insufficient for an expert to simply rely on or parrot another expert's report prepared solely for litigation." *Crescenta Valley Water Dist. v. Exxon Mobile Corp.*, No. CV 07-2630-JST (ANX), 2013 WL 12120533, at *2 (C.D. Cal. Mar. 14, 2013). "Moreover, more scrutiny will be given to an expert's reliance on the information or analysis of another expert where the other expert opinions were developed for the purpose of litigation." *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prod. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013).

Tracking the opinions contained in Dr. Kessler's report, the Doctors state that "it is critically important that manufacturers of IVC filters continuously apprise the clinicians who order and implant IVC filters about their safety profile, performance characteristics, design problems, and internal risk assessments." (Mot. Ex. A, Rep., at pp. 6-7.) Plaintiffs argue that this is based on the Doctors' clinical experience, even though these categories of information are non-clinical. Moreover, the Doctors testified that this statement, referring to internal testing and quality assurance documents, was based solely on their

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personal opinions after reading Dr. Kessler's report. (Ex. A, Streiff Dep., at 277:10 – 278:17 (testifying that he is not basing these opinions "on any particular regulation, standard, or law" and that they are "[a]ll personal opinions based on reading the Kessler report.")); (Mot. Ex. C, Streiff Dep. 274:23 – 277:5 (testifying that "that's not from literature. That's from Dr. Kessler's report"); Mot. Ex. D, Garcia Dep. 193:6-9 (testifying "this is a statement that could apply to the manufacturer of any device or medication that's going to be prescribed or deployed by a treating physician").) In other words, the Doctors' opinion is that Bard should have disclosed what Dr. Kessler says Bard should have disclosed to physicians. For the same reasons that the Doctors cannot be a conduit for Dr. Kessler's opinions, such as failing to independently evaluate Dr. Kessler's opinions, this "physician expectations" opinion should be excluded.

2. The Doctors' General IVC Filter Efficacy Opinion Lacks Relevance And Is Unhelpful to the Jury.

The Doctors also state under the "Physician Expectations" section of their report that "questions remain as to whether [IVC filters generally] are effective." (Mot. Ex. A, Rep., at pp. 6.) Bard agrees that in the proper context, evidence regarding the efficacy of IVC filters generally would be admissible. But, Plaintiffs argue a different issue: that Bard should have warned physicians regarding an alleged lack of efficacy of all IVC filters. (Pl. Br. at 9.) Plaintiffs do not explain how this opinion, which has nothing to do with physicians' expectations regarding *Bard's* filters, is relevant to their warning claim or helpful to the jury. *See e.g., Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 580 (1993) (holding that Rule 702 "demand[s] a valid scientific connection to the pertinent inquiry as a precondition to admissibility"). Indeed, it is unclear what specific warning the Plaintiffs propose should have been added regarding the efficacy of IVC filters, particularly since the FDA assessed the risks and benefits of IVC filters during each 510(k) review. Moreover, Plaintiffs did not establish that any of the bellwether implanting physicians questioned the efficacy of IVC filters.

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Aside from the opinions copying Dr. Kessler that should be excluded, the Doctors do not provide any manufacturer-specific opinions. (June 21, 2017, Deposition of David Garcia, at 44:16 – 46:10, attached as Exhibit B (testifying that the Doctors' incorporation of Dr. Kessler's opinions is the only portion that compares different manufacturers' filters and agreeing that the rest of the general points in the report are "copied and pasted in the Cook [filter litigation] report" and applicable to IVC filters generally)). Indeed, the Doctors do not even opine that all IVC filters are ineffective; only that they are overprescribed. (Mot. Ex. A, Rep., at p. 6 (acknowledging that "[t]he existing literature supports the use of vena cava filters in one setting: acute venous thromboembolism with a contraindication to anticoagulation").) As a result, all of the Doctors' physician expectations opinions should be excluded. *See e.g., Johnson v. Wyeth LLC*, No. CV 10-02690-PHX-FJM, 2012 WL 1150857, at *3 (D. Ariz. Apr. 5, 2012) ("[P]laintiff has not presented any evidence suggesting that [the prescribing physician] was ever exposed to Wyeth's marketing efforts. Without a link between Wyeth's marketing and plaintiff's prescribing doctor, Dr. Hollon's opinions about the subtle effects of marketing on prescribing practices are irrelevant."); *In re Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 5173568, at *6 (N.D. Ohio June 18, 2010), *aff'd sub nom. Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014) ("A generic expert testifying at length about how NSF is diagnosed and how other conditions, such as diabetes, complicates NSF diagnosis is not relevant unless the particular plaintiff has diabetes and a case-specific expert testifies that the plaintiff does not have NSF. In that case, the generic expert's testimony would be superfluous.").

C. Dr. Garcia Did Not Use Reliable Methodology or Analysis for Jones-Specific Opinions.

Plaintiffs concede that Dr. Garcia based his opinion on his observations of *whole* IVC filters promoting thrombosis (Pl. Br. at 9), but do not address Bard's argument that Dr. Garcia provides no basis or methodology to extrapolate an entire filter causing thrombosis to a single strut fragment causing thrombosis. "District court judges are to

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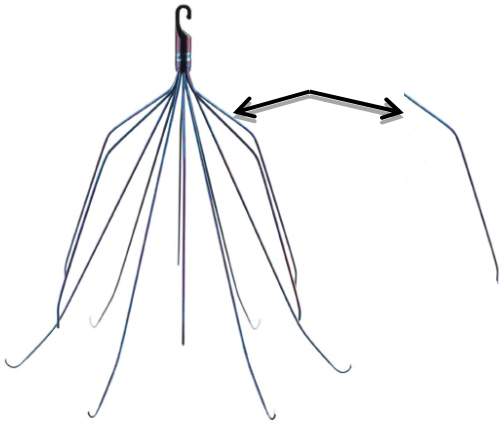
consider not only (1) whether the method has gained general acceptance in the relevant scientific community, but also (2) whether the method has been peer-reviewed, (3) whether the method 'can be (and has been) tested,' and (4) whether there is a 'known or potential rate of error.'" *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 597 (9th Cir. 1996) (citation omitted). The fractured strut in Plaintiff Jones' case is less than nine percent of the material of a whole filter (the Eclipse has 12 struts total), is a different shape than a whole filter, and is located in a different artery of the body with different blood flow.



Plaintiffs cannot argue this opinion is reliable based on Dr. Garcia's experience when Dr. Garcia has never seen a thrombus caused by a filter strut in his personal experience or in the medical literature. (Mot. Ex. D, Garcia Dep. at 225:24 – 228:14.) Moreover, he "do[es] [no]t have any evidence" that the size of the foreign body affects whether it will cause thrombosis. (*Id.*) In other words, Dr. Garcia provides no scientific basis that a single strut of a filter can cause thrombosis. This is precisely the type of "junk science" that *Daubert* and Rule 702 were designed to keep from reaching a jury. *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1229 (9th Cir. 1998) ("To claim that such inert [collagen medical device] objects may cause lupus surely would be 'junk science.'"); *cf. Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1199 (9th Cir. 2014) ("While the district court must act as a gatekeeper to exclude 'junk science' under *Daubert*, Federal Rule of Evidence 702(a)

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includes within its scope all evidence that would 'help the trier of fact ... to determine a fact in issue.' A doctor using a differential diagnosis grounded in significant clinical experience and examination of medical records and literature can certainly aid the trier of fact and cannot be considered to be offering 'junk science.'"). Finally, this opinion that a single strut can promote thrombosis is another generic IVC filter opinion that is unhelpful due to its lack of specificity to Bard's IVC filters (and inappropriate for a "case-specific" opinion).

Lastly, Bard argued that Dr. Garcia's opinion that Plaintiff Jones should be anticoagulated should be excluded because he did not have an understanding of her medical condition, did not recall any of the relevant facts of her medical history during his deposition, and could not testify one way or the other, contrary to his report, that Plaintiff Jones should receive anticoagulation. Plaintiffs' response is merely that differing medical opinions should be submitted to the jury. (Pl. Br. at 10-11.) However, this is not an issue of differing medical opinions. This is an issue of Dr. Garcia's failure to reliably review Plaintiff Jones' medical records and prepare a methodologically sound treatment plan. Dr. Garcia admitted that "active GI bleeding would be a reason you – that one has to withhold anticoagulation, at least until the cause of the bleeding is sorted out and it's treated," but he did not "remember the specific outcome" in Plaintiff Jones' case. (Mot. Ex. D, Garcia Dep. at 222:14 – 223:3.) Even Plaintiff Jones' other medical expert, Dr. Muehrcke, admitted that Plaintiff Jones is contraindicated and cannot be given anticoagulation. (July 24, 2017, Deposition of Derek Muehrcke, at 136:20-23, attached as Exhibit C.) All other experts are in agreement, besides Dr. Garcia who could not recall Plaintiff Jones' medical history, that Plaintiff Jones is contraindicated for anticoagulation. As a result, all of Dr. Garcia's case-specific opinions should be excluded.

CONCLUSION

The Doctors' opinions based on their brief review of Dr. Kessler's report, including their opinions regarding physician expectations, are not only inadmissible under Rule 702, but are also unhelpful and unreliable under *Daubert*. And, Dr. Garcia's opinions in

Plaintiff Jones' case lack any scientific support or methodology. Accordingly, these opinions should be excluded in their entirety.

DATED this 18th day of October, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that October 18, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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